HFI-35 NRO 9/9/99

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-99-86

August 25, 1999

Ramon Rodriguez, President
Rusty Anchor Fisheries
5510 Third Avenue
Stock Island, FL 33040

Dear Mr. Rodriguez:

On January 7, 1999, the Florida Department of Agriculture and Consumer Services (FDACS) conducted an inspection of your facility located at 5510 Third Avenue, Stock Island, FL under contract with the Florida District Office of the Food and Drug Administration (FDA). This letter is based on information provided to us by FDACS from that inspection. The inspector documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

> You are required to implement the monitoring procedures listed in your HACCP plan in order to comply with 21 CFR 123.6(b). However, your firm did not follow any of the monitoring procedures listed at the critical control points of receiving, processing, and storage for controlling the food safety hazard of histamine formation in scombroid toxin-forming species of fish.
>
> You are required to have records which contain the actual values and observations obtained during the monitoring of critical control points, in order to comply with 21 CFR 132.6(c)(7). However, you did not have records to document that any of the monitoring procedures were followed at the critical control points of receiving, processing, and storage in your HACCP plan for scombroid toxin-forming species of fish.

The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Douglas D. Tolen/EHT

Douglas D. Tolen
Director, Florida District